Warranty

Verathon Medical® warrants the FloPoint® Elite Uroflow System against defects in material and workmanship as long as it is covered by the Premium Warranty Total Customer Care℠ Plan. This warranty does not cover equipment sold as used.

Damage or loss insurance is availability as part of the Total Reliability℠ Plan. Pursuant to this warranty, a service center authorized by Verathon® will repair or replace units that prove to be defective during the warranty period.

This warranty does not apply if the unit was misused or modified by anyone other than a service center authorized by Verathon®.

The unit must be used in accordance with the instructions contained in this manual. Consumable items are not covered in this warranty and should be used in conformance with Verathon® product specifications.

For further details, consult your Premium Warranty Total Customer Care℠ Plan. Warranty conditions may differ in some countries outside the United States. Contact your local distributor for warranty terms.

Disclaimer of Additional Warranties

There are no understandings, agreements, representations of warranties expressed or implied (including warranties of merchantability or fitness for a particular purpose) other than those set forth in the preceding Warranty section. The contents of this manual do not constitute a warranty.

Some states disallow certain limitations on applied warranties. The purchaser, user, and patient should consult state law if there is a question regarding this disclaimer. This information, descriptions, recommendations, and safety notations in this manual are based upon Verathon® experience and judgment with FloPoint® Elite as of July 2007. The contents of this manual should not be considered to be all-inclusive, or to cover all contingencies.

The physician who directs the use of the FloPoint® Elite Uroflow System at the institution where it is in use is responsible for keeping current with clinical research in uroflowmetry.

Please direct any questions or problems concerning uroflowmetry, using the instrument, or the interpretation of data to the responsible physician.

Contacting Verathon®

The team at Verathon® is committed to modernizing healthcare delivery by putting patients first. Our products support healthcare professionals by providing the reliability, utility, and excellence. For additional product and company information, visit the Verathon® Web site at www.verathon.com. If you have any questions or comments about Verathon® products and services, please contact us at:

Corporate Headquarters (USA)
Verathon Incorporated
20001 North Creek Parkway
Bothell, WA 98011
USA

Toll free: 800.331.2313 (US & Canada Only)
Tel: 425.867.1348
Fax: 425.883.2896
Web: www.verathon.com
Email: customerservice@verathon.com

EC Rep
Verathon Medical B. V. (Europe)
Boerhaaveweg 1
3401 MN IJsselstein
The Netherlands

Tel: +31.30.68.70.570
Fax: +31.30.68.70.512
Web: http://www.verathon.eu/
Email: customerserviceeu@verathon.nl

Verathon Medical Sarl (France)

Office Address:
Espace Europeen de l'Entreprise
2 allée d'Oslo
67300 Schiltigheim
France

Postal Address:
BP 10039
F-67012 Strasbourg Cedex
France

Tel: +33(0)3.88.60.14.02
Fax: +33(0)3.88.60.46.87
Email: info@verathon.fr

Verathon Medical Ltd.
(United Kingdom)
The Granary Manor Farm Courtyard
Aston Sandford, Aylesbury
Buckinghamshire, HP17 8JB
United Kingdom

Tel: +44.1844.299.207
Fax: +44.1844.299.218
Web: www.verathon.co.uk/
Email: customerserviceuk@verathon.co.uk

Verathon Medical K. K. (Japan)
Executive Tower Azabudai 7F
1-4-3 Azabudai
Minato-ku
Tokyo, Japan 106-0041

Tel: +81.03.3560.3501
Fax: +81.03.3560.3502
Email: servicejp@verathon.com

Clinical Application

Definitions, Indications, and Output

Definitions

Uroflowmetry is a diagnostic test in which the patient urinates into a flow sensor connected to a recording device that produces a plot of urine flow rate versus time (the "uroflow curve"). Most Uroflow Systems measure urine flow rate by continuously weighing the urine as it fills a catch vessel and calculating the rate of increase in urine weight. By contrast, the FloPoint® Elite FloSensor contains a disk that spins at a constant speed. When a flow of urine hits the disk, the motor must work harder to maintain the disk spinning at that same speed with the added weight of the urine. The FloSensor measures the amount of power needed to maintain the disk's original speed and uses that measurement to calculate the urine flow rate. The FloSensor also records the total amount of urine discharged by the patient.

Indications

In general, uroflowmetry is used as a screening test to determine which patients with symptoms or clinical conditions involving the lower urinary tract should be referred for further workup (e.g., urodynamics, cystography). The most common clinical application of uroflowmetry is to provide an objective indication of a low urine flow rate caused by bladder outflow obstruction – especially in males with symptoms suggestive of benign prostatic hypertrophy. Uroflowmetry is also often included in the workup of females with urinary incontinence.

Clinical Condition or History Suggestive Of:

- High bladder outlet resistance. Examples include prostatism (the most common indication), lower urinary tract infection and previous lower urinary tract surgery.
- A decompensated bladder or weak detrusor contraction.
- Neurologic impairment of voiding. Examples include multiple sclerosis and spinal cord injury.

Specific Signs and Symptoms:

- Prolonged or interrupted voiding.
- High residual urine.
- Manually assisted voiding (e.g., by applying pressure to the lower abdomen).
- Excessive straining required to void.

FloPoint® Elite Output

The FloPoint® Elite Uroflow System plots urine flow rate in ml/second versus time in seconds. Several measurements are taken from the FloPoint® Elite curve, either manually by the clinician, or automatically by a digital processor.

FloPoint® Interpretation

Limitations and Specific Clinical Applications

A reduced urine flow rate can be caused by either a bladder outlet obstruction or by detrusor hypocontractility. In turn, bladder outlet obstruction can be due either to an anatomical abnormality (e.g., prostatic hypertrophy) or a neurological abnormality (e.g., detrusor-sphincter dyssynergia caused by multiple sclerosis). Therefore, by itself, uroflowmetry cannot determine the cause of a reduced flow rate.

However, many clinicians with uroflowmetry experience contend that uroflowmetry can provide useful clinical information by itself, particularly in men. For example, Boone and Kim[2] state that if a patient complains of a reduced flow of urine, but there are no other signs or symptoms of voiding dysfunction and uroflowmetry is normal, it is unlikely that further urodynamic testing will reveal an abnormality. Chapple and MacDiarmid[3] state: “Simple uroflowmetry by itself is adequate investigation for uncomplicated prostate-mediated bladder outflow obstruction in over 60% of patients. McLoughlin, et al[5] found that an abnormally reduced maximum urine flow rate is a reliable indicator of obstruction in over 90 percent of men with prostatic symptoms. Also, Abrams[1] and Sand and Ostergard[7] state that in female patients with urinary incontinence an abnormally high flow rate and short duration void sometimes provides a useful suggestion of detrusor instability and/or abnormally reduced outlet resistance.

Quantitative Measurements

Figure 33 diagrams the measurements taken from the FloPoint® Elite curve. Table 1 summarizes the definitions and normal results of these measurements.

Flow Rates

Both maximum and average urine flow rates are strongly dependent on voided volume and the patient's age and sex.

NOTE: In subsequent FloPoint Elite Report Charts (Figure 33 through Figure 42), flow rate is represented by the letter Q.

Figure 33. Measurements Taken From the FloPoint® Elite Curve
A. Measurements of the continuous uroflow curve. Average flow rate (not shown) is calculated by divided total volume voided by flow time. **B.** Measurements of flow time and voiding time from an intermittent uroflow curve.

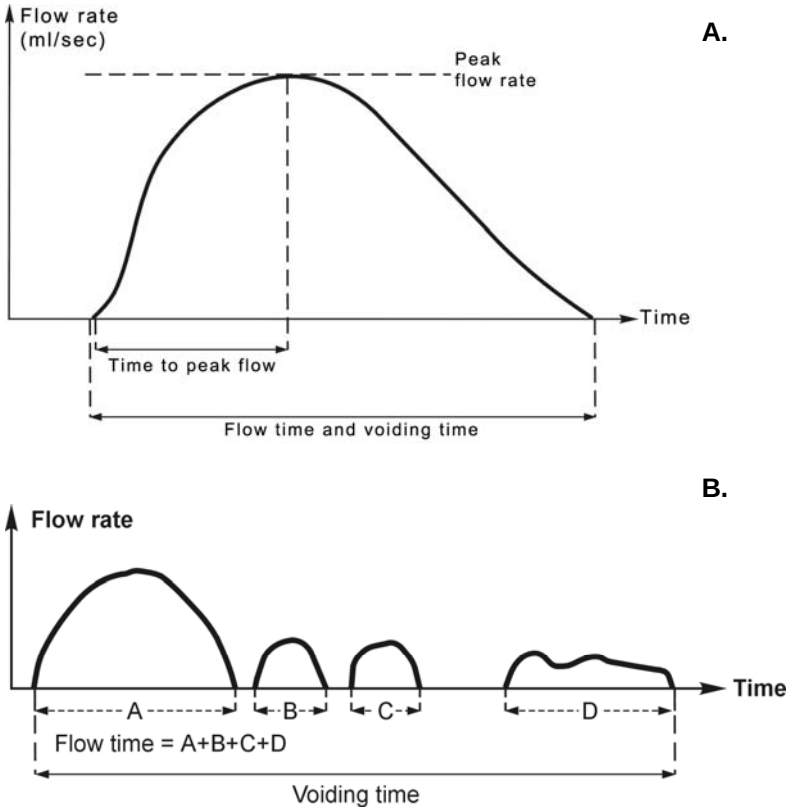


Table 1. Measurements from the FloPoint® Elite Curve (see Figure 33)

MEASUREMENTS	DEFINITION	NORMAL RESULTS
Peak Flow Rate	Maximum measured flow rate excluding dribble-produced or other spikes.	Depends on age, sex and voided volume. Rarely exceeds 40 ml/sec. Clinical significance is questionable with irregular flow patterns.
Average Flow Rate	Voided volume divided by flow time.	Typically is about half of Peak Flow.

MEASUREMENTS	DEFINITION	NORMAL RESULTS
Voiding Time	Total duration of the micturition, including interruptions.	Averages about 10 seconds with 100 ml voided volume and 25 seconds with 400 ml voided volume. No “normal limits” defined.
Flow Time	Total duration of measurable flow.	Equal or nearly equal to voiding time. A flow time that is significantly shorter than the voiding time indicates an abnormal intermittent FloPoint® Elite pattern.
Time to Peak Flow	Time from flow onset to peak flow.	About 30 percent of voiding time. Has no clinical significance with irregular flow pattern.

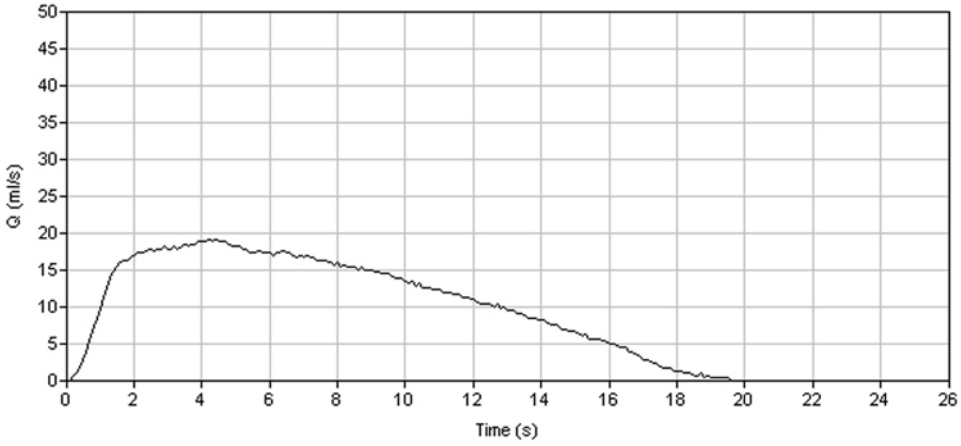
Measurements Related to FloPoint® Elite Curve Patterns

Time to peak flow rate, flow time and voiding time do not provide the same quantitative “normal” versus “abnormal” results as do flow rates. However, as discussed in the next section, these measurements can provide useful indications of the FloPoint® Elite curve’s shape.

Continuous/Regular Patterns:

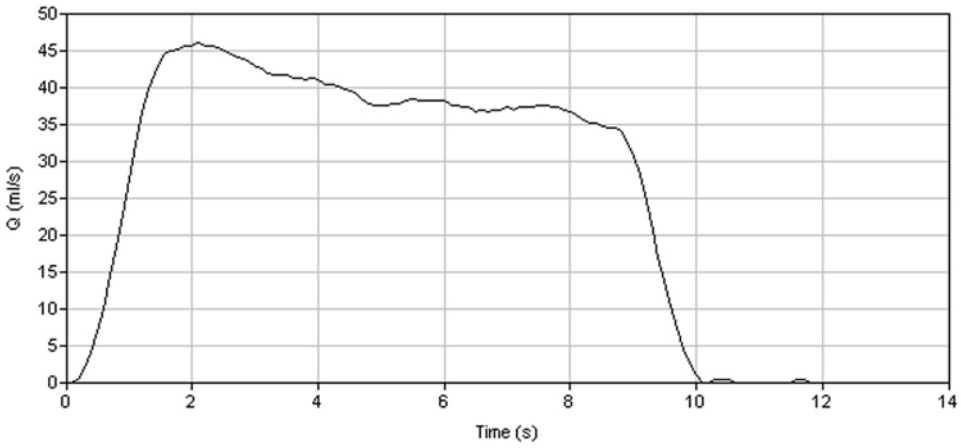
- **Normal:** A normal FloPoint® Elite pattern is a smooth unbroken, bell-shaped curve with peak flow occurring relatively early. (Time to peak flow averages about 30% of total flow time.) Figure 34 shows an example of a normal uroflow curve.

Figure 34. Normal Uroflow Curve



- **Superflow:** Figure 35 shows an example of a “superflow” pattern. This pattern is characterized by a very high flow rate - usually greater 40 ml/sec. - and a very short flow time. A superflow pattern is usually seen in females. It suggests decreased outlet resistance and/or detrusor instability, hence may be associated with urinary incontinence.[2, 6]

Figure 35. Superflow Pattern



- **Obstructive:**
  Patterns suggestive of bladder outlet obstruction (BOO) are characterized by a prolonged flow time during which a large part of the total voided volume is voided at a constant low flow rate. Figure 36 and Figure 37 show examples of “obstructive” flow patterns.

Figure 36. "Flat Top" Obstructive Flow Pattern
The peak on the spike at the end of the trace might have been misinterpreted by the uroflowmetry as the peak flow.

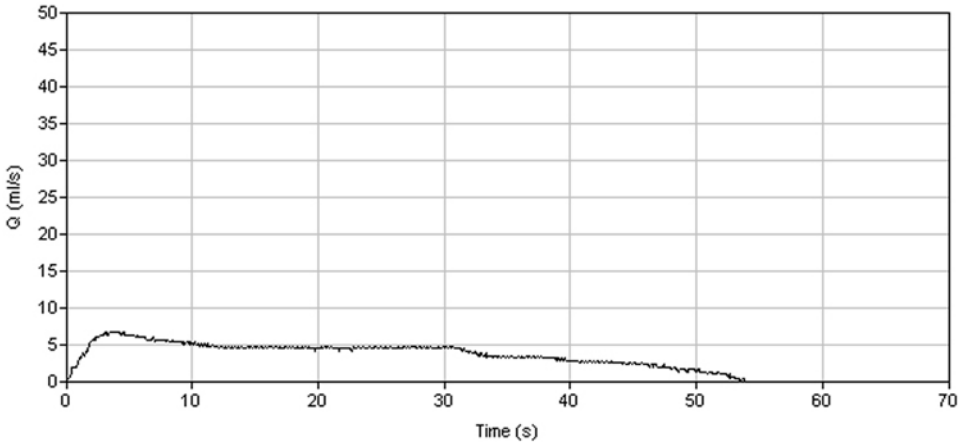
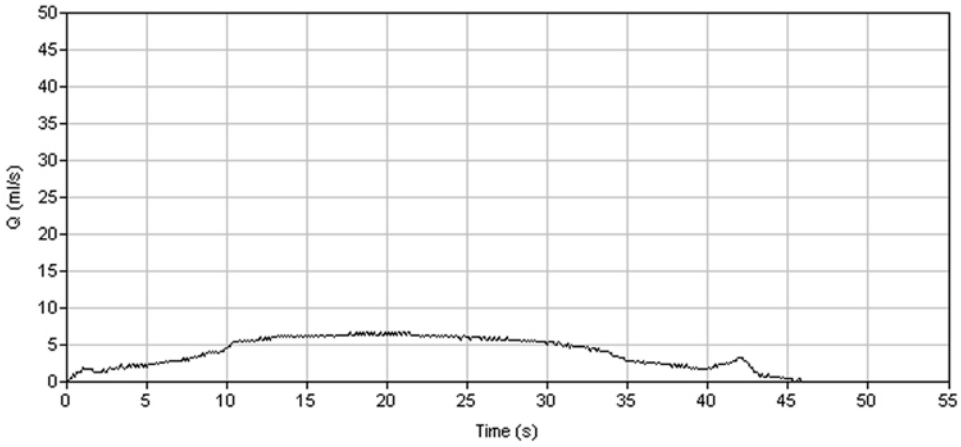


Figure 37. Rounded Top Obstructive Flow Pattern



Irregular Patterns

With the exception of an occasional terminal spurt (e.g., Figure 36) or one or two secondary voids in a normal man, irregular flow patterns are always either abnormal or artifactual. There are two types of irregular flow patterns: a “fluctuating” flow pattern, in which the repeated downward deflections do not fall below a measurable flow rate, and an “intermittent” flow pattern characterized by the occurrence of interruptions of varying durations between voiding episodes. Figure 38 shows an example of a fluctuating flow pattern caused by abdominal straining: Figure 39 shows an example of an intermittent flow pattern caused by detrusor-sphincter dyssynergia.

Figure 38. Fluctuating Pattern Caused by Abdominal Straining

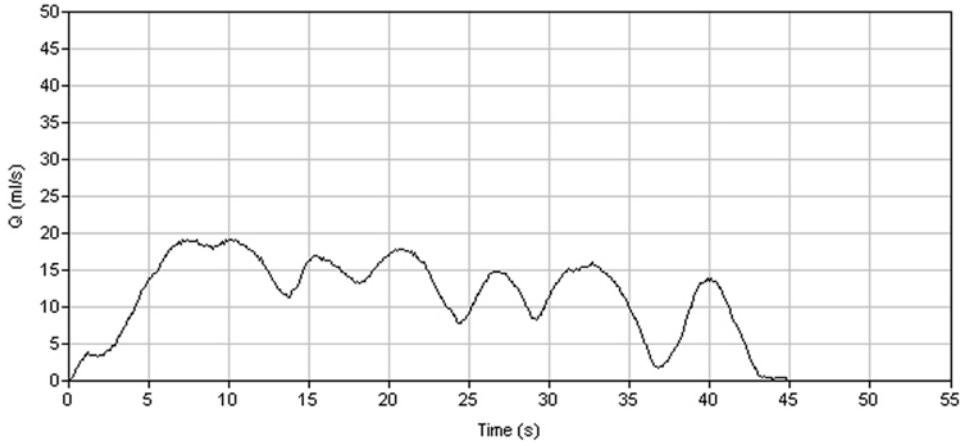
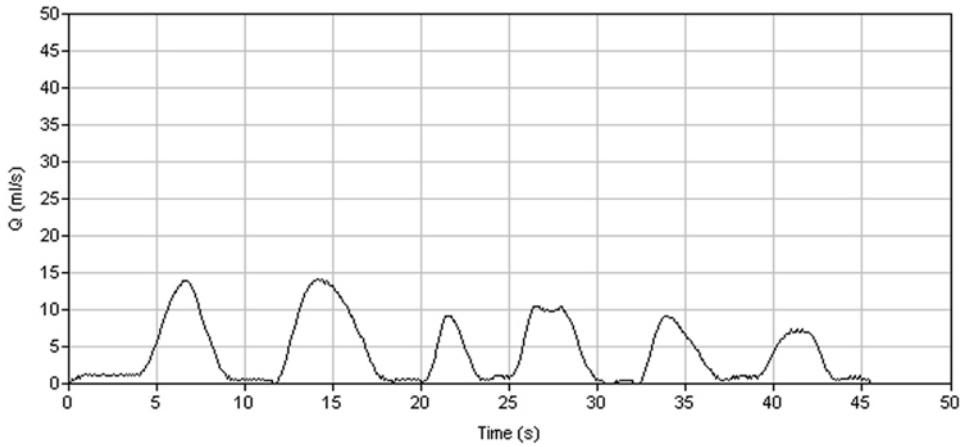


Figure 39. Abnormal Intermittent Pattern, Caused By Detrusor Sphincter Dyssynergia



Clinical Significance

Whether an irregular uroflow pattern or urethral sphincter relaxation are lost causing the detrusor to push intermittently against a contracted urethral sphincter, irregular traces can also be caused by fluctuating or poorly sustained detrusor contractions, which are generally seen in patients with a neurological abnormality – most commonly multiple sclerosis.[1]

Artifactual Causes

As discussed previously, irregular traces can be caused by a male patient moving his stream across to the collecting funnel (“cruising”) or intermittently squeezing the tip of the penis or foreskin during voiding.[1] Figure 40 and Figure 41 show examples of these two types of artifactual irregular patterns. Anxiety, as might be caused by the unfamiliar laboratory environment, can also cause an irregular trace in normals.

Figure 40. Artificial Fluctuating Pattern
The patient creates this pattern by repeatedly moving his stream across the commode outlet.

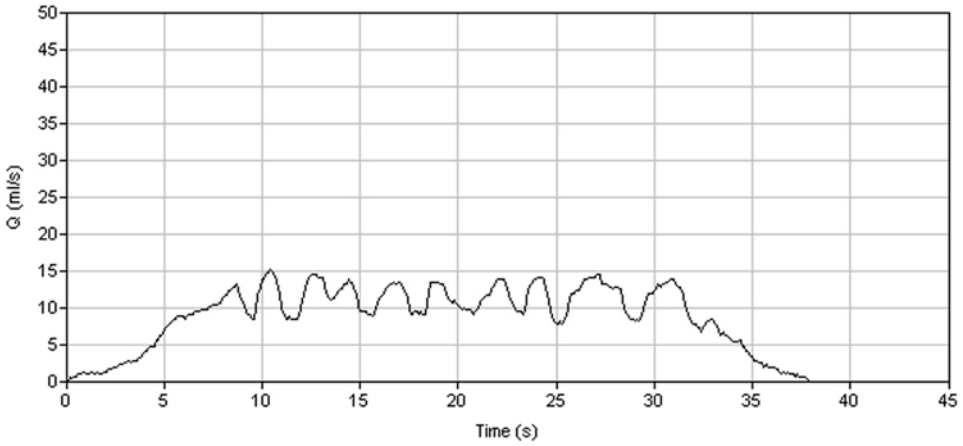
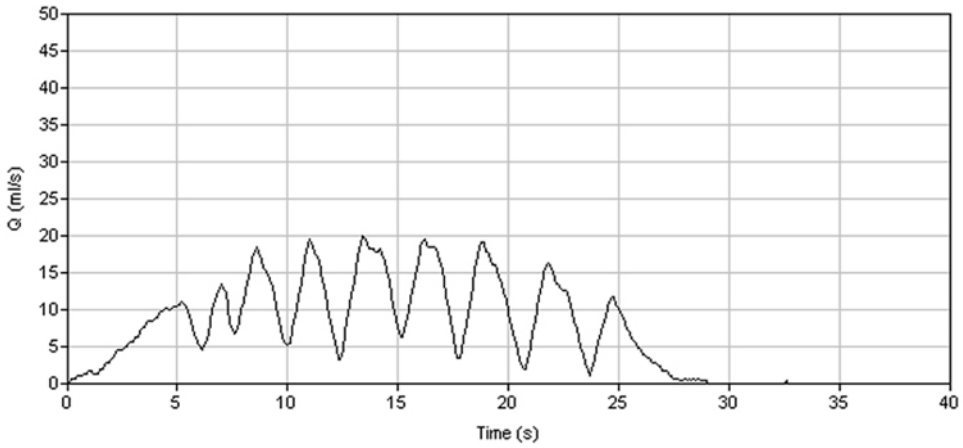


Figure 41. Artificial "Squeezing" Pattern
The patient creates this pattern by repeatedly obstructing urine flow by squeezing his foreskin or penis.



Using Flow Time and Voiding Time to Help Identify the Curve Pattern

A long time to peak and a long flow time can help confirm a subjective impression of an “obstructive” flow pattern.

Comparing flow time with total voiding time provides a quantitative indication of an interrupted flow pattern’s severity – the greater the difference between voiding and flow times, the more severe the interruption.

Summary of Diagnostic Significance

Table 2 summarizes the diagnostic significance of abnormal FloPoint® Elite test results.

Table 2. Diagnostic Significance of FloPoint® Elite Results

CURVE SHAPE		PEAK FLOW	TIME TO MAXIMUM	VOID TIME	CONCLUSION
Pattern	**Shape**				
Continuous	Flat ("obstructive" pattern)	Low	Shortened (Peak flow may be difficult to identify.)	Prolonged	Outlet obstruction*
Continuous	Rounded ("obstructive" pattern)	Low	Variable	Normal	Detrusor under-activity
Continuous	High Peak short duration and ("superflow" pattern)	High	Shortened	Shortened	Detrusor instability and/or normal or reduced output resistance
Irregular**	Fluctuating	Variable	No significance	No significance	Voluntary abdominal straining. Detrusor-sphincter dyssynergia. Dysfunctional voiding
Irregular	Interrupted	Variable	No significance	No significance	Same as fluctuating pattern. Possibly a more severe condition.

* In female, rule out stress urinary incontinence and lower urinary tract infection.
** In male, rule out "cruising", (variable stream direction) and intermittent squeezing of penis or foreskin.

Artifacts and Pitfalls

Following are some events and conditions that can lead to misinterpretation of FloPoint® Elite test results.

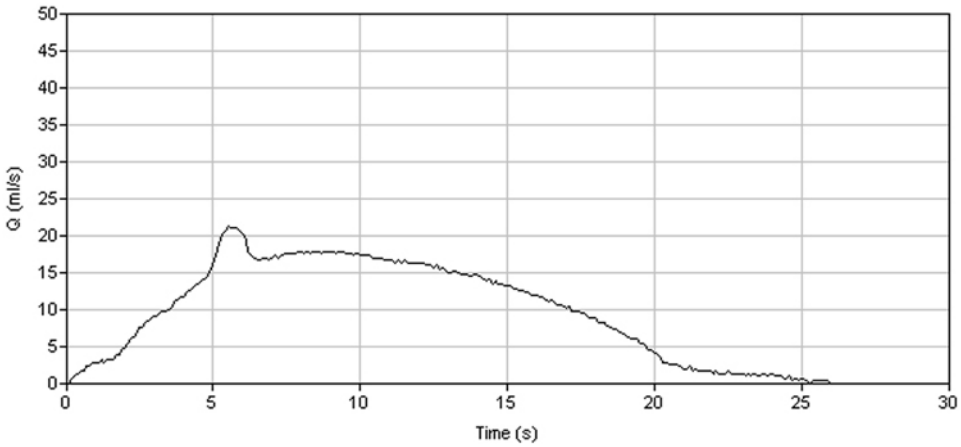
"Spikes" or Rapid Fluctuations in the Curve

There are several potential causes of spikes in the FloPoint® Elite curve that can lead to misinterpretation. The most common of these are: (1) mechanical disturbance of the flow sensor and, (2) straining either during (Figure 42) or at the end (Figure 38) of the void.

The most significant misinterpretation that can be caused by spikes is mistaken identification by an automatic processor of a spike peak as the void maximum.[1,2,4,6]

Figure 42 shows examples of such a computer misinterpretation (solid arrow). In situations such as this, the clinician must override the computer's interpretation and read the maximum manually from a smooth portion of the uroflow trace (open arrow in Figure 42).

Figure 42. Artifactual uroflow peak produced by a spike
The (black arrow) identifies an artifactual spike that the uroflowmetry reads as the flow peak. The correct peak flow (open arrow) must be read manually by the interpreter.



Low and High Voided Volumes

When total voided volumes are below 150 ml, "normal" flow rates become so low as to make the test an insensitive indicator of an abnormally low flow rate. At voided volumes of over 600 ml, the bladder may become decompensated, thereby producing an artifactually low flow rate.[1] Therefore, it is important to avoid voided volumes below 150ml and above 600ml. If such volumes are encountered, the test should be repeated.

Test Technique

Incorporating the following into the FloPoint® Elite test procedure will materially enhance both the efficiency with which the test is done and the clinical utility of the test's results:

1. The void should be performed with a comfortably full bladder. To accomplish this, the patient should be instructed to drink approximately 2 pints of fluid two hours before appearing for his or her appointment and to not void prior to arriving at the clinic. Alternatively, the patient might be questioned about the fullness of his bladder upon arriving for his appointment and instructed to drink water immediately if the bladder is empty. As noted above, voids of more than 600 ml or less than 150 ml should be repeated as the patient's bladder has refilled.
2. Instruct the patient to void in a position that he or she is most used to (usually standing for a male, sitting for a female).
3. A male should be instructed to direct the stream to the location marked on the funnel and to maintain constant stream direction throughout the void.

Reimbursement Information

Physician Participation Requirement

During the performance of FloPoint® Elite uroflowmetry, "direct physician supervision" is required. This means that the physician must be present in the office suite (not necessarily in the room when the procedure is performed), and immediately available to furnish assistance and direction throughout the performance of the procedure.

Procedure Codes

There are only two procedure codes to use for the performance of FloPoint® Elite uroflowmetry:

51736: Simple uroflowmetry (uroflowmetry performed by the use of stop-watch flow rate or a mechanical Uroflow System).

51741: Complex uroflowmetry (uroflowmetry performed using calibrated electronic equipment).

Diagnosis Codes

Table 3 lists diagnosis codes that can be entered into a claim for FloPoint® Elite uroflowmetry reimbursement. Diagnosis codes for uroflowmetry that are acceptable to regional reimbursement bodies differ by region. Therefore, specific regions may not authorize uroflowmetry reimbursement for all listed diagnosis.

Table 3. Diagnosis Codes Used with FloPoint® Elite

DIAGNOSIS	CODE
Equina syndrome with neurogenic bladder	344.61
Atony of Bladder	596.4

DIAGNOSIS	CODE
Bladder Neck Obstruction (acquired)	596.0
Hypertonicity of bladder	596.51
Low bladder compliance	596.52
Paralysis of bladder	596.53
Neurogenic bladder NOS	596.54
Detrusor sphincter dyssynergia	596.55
Other functional bladder disorder	596.59
Urethral stricture due to unspecified infection	598.00
Traumatic urethral stricture	598.1
Postoperative urethral stricture	598.2
Other specified causes of urethral stricture	598.8
Urethral stricture, unspecified	598.9
Hypertrophy of prostate (BPH)	600.0
Retention of urine, unspecified	788.20
Incomplete bladder emptying	788.21
Other unspecified retention of urine	788.29
Urinary incontinence, unspecified	788.30
Urge incontinence	788.31
Stress incontinence, male	788.32
Mixed incontinence	788.33
Incontinence w/o sensory awareness	788.34
Post-void dribbling	788.35
Nocturnal enuresis	788.36
Continuous leakage	788.37
Other urinary incontinence	788.39
Urinary frequency (micturition)	788.41
Polyuria	788.42
Nocturia	788.43
Splitting of urinary stream (intermittent)	788.61
Slowing of urinary stream (weak)	788.62

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2. Boone T.B. and Y. H. Kim, Chapter 4, Uroflowmetry, in Nitti, V. D. (ed), Practical Urodynamics, Philadelphia, W. B. Saunders, 1998, pages 28-37.
3. Chapple, C.A. and S. A. MacDiarmid, Urodynamics Made Easy, Chapter 3 Urodynamic Techniques: Flow Rate, New York, W.B. Saunders, 2000, pages 26-32.
4. Grino, P., B., et al, Maximum urinary flow rate by uroflowmetry: automatic or visual interpretation, J. Urol, 149, 339-341, 1993.
5. McLoughlin, J., et al, Symptoms versus flow rates versus urodynamics in the selection of patients for prostatectomy, Brit. J. Urol. 66, 303-305, 1990.
6. Rivas, D. A. and M. B. Chancellor, Chapter, 5, Uroflowmetry, in Blaivis, J., and M. Chancellor, (eds.), Atlas of Urodynamics, Baltimore, Williams & Wilkins, 1996.
7. Sand, P. K. and D. R. Ostergard, Urodynamics and the Evaluation of Female Incontinence, A Practical Guide, Chapter 3, Uroflowmetry in the Female, London, Springer-Verlag, 1995.

Parts and Accessories

FloPoint® Elite Uroflow System Components

The following components are included with your FloPoint® Elite Uroflow System with ScanPoint® with QuickPrint system.

Part and Part Number	Name and Description
 0570-0175 - FloSensor	**FloSensor** Measures urine volume and flow rate. The Handles suspend the FloSensor inside the toilet.
 0570-0176 - FloCharger	**FloCharger with Clamshell:** Stores the FloSensor, recharges the batteries, and resets the measuring device to zero.
 0800-0337	**FloPoint® Elite Mounting Bracket:** Attaches to the wall, securely holding the FloCharger and a funnel box 3 feet (0.914 m) or more above the floor.

Part and Part Number	Name and Description
 0570-0174	**ScanPoint® Remote:** Acts as a remote control to start and stop the FloSensor, displays information on flow measurements and device status, and records voice annotation.
 0570-0168	**ScanPoint® Docking Station:** Transmits data from the ScanPoint® Remote to the ScanPoint® host computer and recharges the Remote batteries.

To order any of the above parts, contact your authorized Verathon Medical® Sales Representative or contact the Verathon Medical® Customer Care Department at 1.800.331.2313.

FloPoint® Elite Uroflow System Accessories

The following accessories are included with your FloPoint® Elite Uroflow System with ScanPoint® with QuickPrint system.

Part and Part Number	Name and Description
 0900-1238	**ScanPoint® with QuickPrint Installation CD:** Produces reports based on the data gathered during an exam and submitted by the ScanPoint® Remote.
 0900-1445	**FloPoint® Elite In-Service CD** Includes FloPoint® Elite User's Manual and Quick Reference Cards.

Part and Part Number	Name and Description
 0800-0297	**Box of Paper Funnels:** Help direct the urine flow toward the FloSensor. Box contains 40 funnels.
 0130-0181	**Activation Tool:** Use to press the Reset button on the ScanPoint® Remote if the Remote needs to be reactivated.
 0264-0008	**Lanyard:** Attaches to the ScanPoint® Remote, if desired, to assist with placement of the Remote in proximity to the FloSensor
 0900-1443	**FloPoint® Elite Setup and Use Quick Reference Card:** Provides a summary of essential operator instructions.
 0900-1444	**FloPoint® Elite Calibration Quick Reference:** Provides instructions for the FloPoint® calibration procedure.

Part and Part Number	Name and Description
 0900-1557	**FloPoint® Elite Mounting Bracket Template** Aids in attaching the Mounting Bracket to the wall.

To order any of the above parts, contact your authorized Verathon Medical® Sales Representative or contact the Verathon Medical® Customer Care Department at 1.800.331.2313.

Other FloPoint® Elite Uroflow System Accessories

The following accessories are not included with your FloPoint® Elite Uroflow System with ScanPoint® with QuickPrint system.

Part and Part Number	Name and Description
 0800-0331	**Calibration Fluid Pouches:** Pouch containing unique fluid for use in calibrating the FloPoint® Elite. The Calibration Fluid Pouches are shipped with the Calibration Kit.
ScanPoint® Label Writer and Related Components	
 0570-0178	**ScanPoint® Label Writer (optional):** Prints exam results.

Part and Part Number	Name and Description
 0600-0233	**USB Cable:** Connects the ScanPoint® Label Writer to the ScanPoint® host computer.
 0275-0002	**Switching Power Adapter:** Connects the Label Writer to the wall outlet.
 0125-0446	**Roll of Labels:** Labels in roll format properly sized for the ScanPoint® Label Writer.
 0600-0232	**Power Cord:** Connects the FloCharger to the wall outlet to charge the FloSensor battery.

To order any of the above parts, contact your authorized Verathon Medical® Sales Representative or contact the Verathon Medical® Customer Care Department at 1.800.331.2313.

Specifications

Symbol Directory

The following table illustrates and explains the symbols that may appear on the FloPoint® Elite Uroflow System components and/or packaging. These symbols indicate the FloPoint® Elite system compliance with international and national standards and regulations.

Symbol	Meaning
	Underwriters Laboratories mark of certification of the FloPoint® Elite uroflow system with respect to electrical shock, fire and mechanical hazards only in accordance with UL 60601-1 and CAN/CSA 22.1 No. 601.1
	IEC 348 symbol indicating "Attention, consult accompanying documentation."
	Marked in accordance with Directive 2002/96/EC on Waste Electrical and Electronic Equipment (WEEE) (solid bar indicates product was put on the market after 13 August 2005.
	Protection Class II equipment, internally powered equipment.
	Type BF applied part with EN/IEC-60601-1.
	CE marked in accordance with the Medical Device Directive (MDD).
	Canadian Standards Association (CSA) mark of certification to United States standards for electromedical equipment.

Standards and Regulations Compliance

Verathon® certifies that all units are in compliance with all applicable international and national standards and regulations, including but not limited to the following:

Specification	Standard
Electromagnetic compatibility standards	IEC 60601-2, ICES-001
Safety Standard	IEC 60601-1
Health Insurance Portability and Accountability Act (HIPAA)*	

*For details on Verathon® compliance with privacy rules, please refer to the information in the QuickPrint Help menu (select “Privacy Agreement”).

Electromagnetic Effects

There are no restrictions on the use of FloPoint® Elite Uroflow System due to its electromagnetic characteristics. Both the emissions from FloPoint® Elite and the susceptibility of this instrument to interference from other sources are within prescribed limits of all applicable standards at the date of manufacture. The emissions test procedure that was used is specified in EN/IEC55011: 1991 for Group 1, Class A equipment (per EN/IEC60601-1-2, 36.201.1.7).

This ISM device complies with Canadian ICES-001.
Cet appareil ISM est conforme à la norme NMB-001 du Canada.

NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

-- Reorient or relocate the receiving antenna.

-- Increase the separation between the equipment and receiver.

-- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

-- Consult the dealer or an experienced radio/TV technician for help.

Modifications to this equipment not expressly approved by Verathon® could void the user's authority to operate the equipment

FloPoint® Elite Uroflow System is suitable for use in industrial, scientific, and medical (ISM) environments, and in domestic environments under the jurisdiction of a health care professional. An indication of adverse electromagnetic effects from FloPoint® Elite Uroflow System on another electronic device would be a degradation of performance in the other device when the devices are operated simultaneously. If such interference is suspected, separate the two devices as much as possible, or discontinue simultaneous operation, if practical, and contact Verathon®.

The FloPoint® Elite Uroflow System will operate normally in the proximity of other potential interference sources, and has demonstrated immunity at a field strength of 3 V/m (per EN/IEC 60601-1-2, 36.202.2.1). You do not need to take any other precautions

regarding exposure in reasonably foreseeable environmental conditions to magnetic fields, pressure, or variations in pressure, acceleration, or thermal ignition sources.

Health Insurance Portability and Accountability Act

To address the growing concern about the protection and confidentiality of an individual's medical information, Verathon® has taken the following measures to ensure the safe delivery and storage of all information that is maintained, used, and presented by the ScanPoint® system:

- All ScanPoint® system communications across the Internet are transmitted using the Secure Socket Layer (SSL) protocol and the 128-bit Data Encryption Standard (DES).
- All Patient Health Information (PHI) specific data stored within the ScanPoint® database is encrypted.
- The ScanPoint® Web site infrastructure is housed by a Tier-1 Network Service Provider (NSP) that meets the SAS/70 certification.
- Within the NSP, the ScanPoint® equipment is located in a "locked, steel cage" structure, removing access from even the NSP's personnel.
- Verathon® has enacted all policies and procedures outlined in HIPAA to protect our internal network from unauthorized access.

Verathon® has taken these actions to meet HIPAA's Privacy and Security requirements and shall continue to monitor any changes in these laws to insure all precautions are taken to protect PHI. For further information on how Verathon® manages access to PHI, refer to the Verathon® Business Associate Agreement (0003-0138).

FloCharger

Item	Specification
Input Voltage	100 – 240 V AC RMS
Input Frequency	50 – 60 Hz
Input current	2 A max
Input connection	Employs direct plug-in AC prongs for wall outlets.
Insulation	Class II with double insulation to each terminal.
Testing	To EN/EN/IEC 60601-1 requirements
Water Ingress	Rated at IPX0 (not protected against ingress of water)
Compliance	UL and CSA equivalent standards

FloSensor

Item	Specification
Sensory Type	Spinning Disk
Battery type	Lithium Ion. 14.4 V, 2200 mAh
Battery life	A fully charged battery can perform approximately 30 exams within a 24-hour period.
Charging Method	Charge the FloSensor using the FloCharger installed on the Mounting Bracket.
Charging Time	No more than six hours from an empty battery to a full charge.
Water Ingress	Rated at IPX7 (Water tight for 30 minutes at a depth of 1 m)

ScanPoint® Remote

Item	Specification
Battery type	Lithium Ion. 4.2 V, 700 mAh
Battery life	A fully charged battery can perform approximately 30 exams within a 24-hour period.
Charging Method	Charge the FloSensor using the ScanPoint® Docking Station connected to the USB port of a computer compliant with IEC 60950 or IEC 60601-1.
Charging Time	No more than eight hours from an empty battery to a full charge.
Water Ingress	Rated at IPX0 (not protected against ingress of water)

ScanPoint® Docking Station

Condition	Specification
Use	Indoor
Water Ingress	Rated at IPX0 (not protected against ingress of water)

Condition	Specification
Computer Regulatory Compliance	The computer must minimally comply with the requirements of IEC 60950 and preferable with the requirements of IEC 60601-1.
Computer Connection	USB 1.1
Design	Decoupled transformer at 200 mA at 4.2 V (25 kHz)
Water Ingress	IPX0

Accuracy Specifications

The accuracy specifications assume the instrument is being used according to the instructions provided by Verathon®.

Specification	Description
Flow rate measurement	± 3% ± 1 ml/s (as measured by Verathon® accuracy measurement test)
Volume measurement	± 3% ± 5 ml/s (as measured by Verathon® accuracy measurement test)
Maximum Flow Rate	50 ml/s
Maximum volume measure	2 liters

Operating Conditions

All components of the FloPoint® Elite Uroflow System are designed to function properly within the following specifications:

Condition	Value
Use	Indoor
Ambient Temperature Range	+10 - +35º Celsius (50 - 95º Fahrenheit)
Atmospheric pressure range	70 kPa - 106 kPa
Relative humidity	30% - 75% non-condensing

Storage Conditions

All components of the FloPoint® Elite Uroflow System are designed to withstand the following storage conditions:

Condition	Description
Storage	Indoor
Ambient Temperature Range	-10 - +35º Celsius (14 - 95º Fahrenheit)
Atmospheric pressure range	50 kPa - 106 kPa
Relative humidity	20% - 95% non-condensing

Radio Specifications

The FloSensor and ScanPoint® Remote communicate via a radio frequency that operates in the 2.4 GHz ISM (Industrial, Scientific, Medical) band with a range of 3 meters (10 feet). FloPoint Elite Equipment complies with the specifications contained in FCC Part 15.

Parameter Description	Condition	Value
RF Frequency Range		2.402 - 2.479 GHz
Range		Up to 3 meters (10 feet)

Computer Hardware and Software Requirements

To use ScanPoint® with QuickPrint, your computer must meet the following hardware and software requirements:

NOTE: ScanPoint® with QuickPrint works only with Microsoft Internet Explorer 6.0 or later.
ScanPoint® with QuickPrint is not compatible with Apple Macintosh computers.

Requirement	Minimum	Recommended
Processor	PC with 800 MHz processor	PC with 2.0 GHz processor
Video display	Video card and monitor capable of 800 x 600 resolution.	Video card and monitor capable of 1024 x 768 resolution.

Requirement	Minimum	Recommended
USB Ports	Two USB 1.1 ports	Two USB 2.0 ports*
Hard drive	50 Mb of available space	5 Gb of available space
Memory	256 Mb	512 Mb
Internet access	256k DSL	512k DSL, cable modem, T1 line or other high-speed connection

Operating System and Software Requirements

Requirement	Minimum	Recommended
Operating system	Microsoft® Windows® 2000 Professional with Service Pack 2	Microsoft Windows 2000 Professional with Service Pack 4, Windows XP.
Browser	Microsoft Internet Explorer® version 6.0	Microsoft Internet Explorer version 7.0
Microsoft .NET Framework	.NET Framework version 2.0 (This software is installed with ScanPoint® with QuickPrint.)	.NET Framework version 2.0 with the latest Microsoft updates installed.
Adobe® Acrobat Reader®	Adobe Acrobat Reader 6.0	Adobe Acrobat Reader 7.0*

*Available for free download from www.adobe.com.

Label Writer Specifications

The ScanPoint® Label Writer meets the following specifications:

Condition	Description
Print method	Direct thermal
Print resolution	300 dots per inch (118 dots per mm)
Maximum print width	2.25” / 56 mm
Maximum media width	2.44” / 62 mm
Interface	USB 2.0 full speed printer class device

Condition	Description
Average print head life	2,000,000 linear inches (over 31 miles) / 50,800 linear meters
Printer power requirements	24 VDC 1.75 A
Regulatory approvals	CE, FCC, cTUVus, GS and C-Tick

Mounting Bracket and Related Equipment Specifications

The ScanPoint® Label Writer meets the following specifications:

Condition	Description
Mounting bracket material	16 guage 304 stainless steel
Weight (mounting bracket alone)	6.5 lb (2.95 kg)
Weight (mounting bracket plus funnels, charger, and sensor	13 lb (5.9 kg)

Glossary

Term	Meaning
Activate	When the ScanPoint® Remote battery has been completely discharged, you may need to activate, or reset, the Remote before you can use it again. The Remote can be reactivated by pressing the recessed Reset button on the back of the unit using the supplied Activation Tool.
Activation Tool	The small tool used to depress the Reset button on the back of the Remote (see “Activate” above).
Annotation	A brief voice recording made on the ScanPoint® Remote providing exam details.
Average Flow	The average flow rate during flow intervals measured in ml/s. This calculation does not include the time between intervals.
Calibration	Checking the accuracy and function of your FloPoint® by comparing it with a known standard.
ScanPoint® Docking Station	The unit that transmits exam data from the Remote to the ScanPoint® host computer, and when the computer is turned on, also charges the Remote battery.
Continuous (Pattern)	There was one flow interval detected during the exam.
Detailed Report	This report contains all ICS values and prints on two labels or a single sheet of 8.5 x 11” paper. It contains: the date and time of the exam, patient ID, patient name, operator ID, physician, gender, position and indicator for whether or not this was a normal flow for the patient, peak flow measurement, average flow measurement, voided volume, flow time measurement, void time measurement, pattern measurement, chart of flow rate vs. time, chart of cumulative volume vs. time, part number and serial number of the FloSensor, and the ScanPoint® exam ID. See also Summary Report.
FloCharger	The FloPoint® Elite base unit that provides a storage and transportation unit for the FloSensor and also recharges the FloSensor batteries.
FloSensor	The central component of the FloPoint® Elite system, it contains a rotating disc for measuring urinary flow rate and volume..

Term	Meaning
Flow Interval Ends	The end of a flow interval is identified by two consecutive samples with a flow rate less that 0.2 ml/s.
Flow Interval Starts	The start of a flow interval is identified by two consecutive samples with a flow rate greater than 0.5 ml/s. The actual start of the interval is selected to be the sample prior to the identifying samples where the flow rate is at least 0.2 ml/s.
Flow Time	The total amount of time in seconds during which flow is being measured. In the case of intermittent flow, this value will be smaller than the Void Time as this value does not include the time between intervals where there is no flow.
HIPAA	Health Insurance Portability and Accountability Act, enacted by the US Congress in 1996. Title II of HIPAA, the Administrative Simplification provisions (AS), requires the establishment of national standards for electronic health care transactions and national identifiers for providers, health insurance plans, and employers. The AS provisions also address the security and privacy of health data. The standards are meant to improve the efficiency and effectiveness of the nation's health care system by encouraging the widespread use of electronic data interchange in the U. S. health care system.
ICS	International Continence Society. An international association of medical professionals whose purpose is to study storage and voiding function of the lower urinary tract, its diagnosis and the management of lower urinary tract dysfunction, and to encourage research into pathophysiology, diagnostic techniques and treatment.
Intermittent (Pattern)	There were two or more flow intervals detected during the exam (see also Continuous and Undetermined).
LCD screen	The LCD (liquid crystal display) screen on the ScanPoint® Remote that displays flow measurements, instrument status, and other exam settings and information.
New Flow Interval Starts	A new flow interval is identified by a Flow Interval Start that is at least 0.25 seconds after the previous Flow Interval End.
Peak Flow	Peak flow rate measured in ml/s. The value of the peak flow detected by the FloSensor (see also Average Flow).
QuickPrint	The program that process exams and prints the results.

Term	Meaning
ScanPoint® Remote	The remote control unit that receives exam data from the FloSensor via radio contact and transmits the exam data to the ScanPoint® host computer via ScanPoint® Remote Docking Station.
ScanPoint® Imaging Technology	The software and online service provided by Verathon® that prints exam results, maintains patient records, displays flow diagrams from exams, downloads software updates, and calibrates the FloPoint® Elite.
ScanPoint® with QuickPrint	ScanPoint® with QuickPrint is a software program installed on your computer that communicates with ScanPoint® Online to help you quickly and easily download and print FloPoint® Elite measurements.
Sleep mode	When the FloSensor and/or ScanPoint® Remote shuts down to conserve energy. Press the ScanPoint® Remote button to “wake up” the device.
Summary Report	Provides only peak flow measurement and prints on a single label or a single sheet of 8.5 x 11” paper. The Summary Report contains the date and time of the exam, patient ID, patient name, operator ID, physician, gender, position and indicator for whether or not this was a normal flow for the patient, peak flow measurement, chart of flow rate vs. time, part number and serial number of the FloSensor, and the ScanPoint® exam ID. See also Detailed Report.
Time to Peak Flow	The amount of time, measured in seconds, between the start of the first interval of flow to the maximum measured flow rate.
Undetermined (Pattern)	There were no flow intervals detected in the exam (see also Continuous and Intermittent).
Void Time	The total amount of time in seconds from the start of the first interval to the end of the last interval, including all the time between intervals where flow is not measured.
Voided Volume	The total volume of urine measured by the FloSensor in ml.

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